

Application Number 10/731,869
Responsive to Office Action mailed February 23, 2006

REMARKS

This submission is responsive to the Final Office Action dated February 23, 2006. Applicant has not amended the claims by way of this submission. Accordingly, claims 1-31 and 33-57 remain pending.

Finality of Office Action Improper

Independent claims 42 and 56 were not amended in Applicant's previous Amendment dated November 28, 2005, but are now being rejected on admittedly new grounds.¹ The finality of the current Office Action is therefore improper and must be withdrawn.

MPEP 706.07(a) defines when it is proper for the Examiner to make an Office Action final. MPEP 706.07(a) provides that:

Second or any subsequent actions on the merits shall be final, except where the Examiner introduces a new ground of rejection that is neither necessitated by Applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c).

In the current case, Applicant did not amend claims 42 and 56 and the references applied by the Examiner as part of the new grounds of rejection were not submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c). Therefore, no action by Applicant necessitated the new grounds of rejection of these claims. Moreover, MPEP 706.07(a) specifically indicates that:

Furthermore, a second or any subsequent action on the merits in any application or patent undergoing reexamination proceedings will not be made final *if it includes a rejection*, on newly cited art, other than information submitted in an information disclosure statement filed under 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p), *of any claim not amended* by Applicant or patent owner *in spite of the fact that other claims may have been amended to require newly cited art*. (Emphasis added)

The same reference, Meltzer (US 5,645,586), that was applied in the previous office action is the basis for the new grounds of rejection. However, in the current Office Action, the Examiner has cited different embodiments disclosed in Meltzer, which are substantially dissimilar to the previously cited embodiments. The Examiner correctly recognized that the citation of these significantly different embodiments of Meltzer in place of the previously cited embodiments is a new ground of rejection. Furthermore, by relying on this new ground of

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rejection from Meltzer, the Examiner avoided responding to the arguments presented by Applicant in the previous Amendment with respect to the previously cited embodiments. Accordingly, in view of above-cited passages from MPEP 706.07(a), the finality of the Office Action is clearly improper and must be withdrawn.

Claim Rejection Under 35 U.S.C. § 102

In the Final Office Action, the Examiner rejected claims 1, 2, 11, 13-17, 19-23, 33-34, 36-42 and 51-55 under 35 U.S.C. § 102(b) as being anticipated by Meltzer. Applicant respectfully traverses the rejection. Meltzer fails to disclose each and every feature of the claimed invention, as required by 35 U.S.C. § 102(b), and provides no teaching that would have suggested the desirability of modification to include such features.

For example, Meltzer fails to disclose or suggest an implantable medical device including first and second modules, each of the modules including a respective one of first and second housings, and an overmold that at least partially encapsulates the first and second housings, as required by each of Applicant's independent claims 1, 23, 39 and 42. In rejecting the independent claims, the Examiner stated:

Meltzer discloses an implantable defibrillator with a flexible housing that surrounds a flex circuit assembly as seen in figure 5. The logic assembly 56 is considered be the first module and the battery 55 is considered to be the second module. The overmold is the flexible housing 50 and 51.²

This statement suggests that the Examiner may have overlooked the requirement in claim 1 of two housings that are at least partially encapsulated by the overmold.

Meltzer does not suggest that either of the logic assembly 56 and the battery 55, much less both, are included within a housing, other than the housing common to both, which the Examiner has interpreted to be the overmold required by each of the independent claims. Elements 50 and 51 described by Meltzer form a single housing, rather than two housings. Therefore, elements 50 and 51 cannot be both an overmold that encapsulates two housings, as argued by the Examiner, and the encapsulated housings themselves. Accordingly, Meltzer does not disclose or suggest an implantable medical device including first and second modules, each

¹ Final Office Action, page 2 (*Response to Arguments*) and page 6 (*Conclusion*).

² Final Office Action, page 3.

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of the modules including a respective one of first and second housings, as required by independent claims 1, 23 and 42.

As another example, independent claim 39 further requires a hermetic interconnect member that flexibly couples the first and second housings. Similarly, claim 34, which depends from independent claim 23, requires a hermetic interconnect member that flexibly couples the first and second housings and defines at least one lumen between the housings. Meltzer fails to disclose or suggest these requirements of claims 39 and 34.

In the Final Office Action, the Examiner argued that the flex-circuit assembly 52 depicted by Meltzer is a flexible interconnect member because it can be manipulated and deformed. The Examiner does not appear to have considered, or at least did not address, the above-identified requirements of a hermetic interconnect in claims 39 and 34, nor at least one lumen. Meltzer does not suggest that the flex-circuit is hermetic or defines a lumen between housings. Accordingly, Meltzer fails to disclose or suggest a hermetic interconnect member that flexibly couples the first and second housings, as required by both of claims 39 and 34, and that additionally defines a lumen between the housings, as required by claim 34.

As another example, independent claim 42 further requires that one of the housings includes both control electronics and a therapy delivery circuit that delivers stimulation as controlled by the control electronics. The Examiner does not appear to have considered this requirement of claim 42. In any event, Meltzer fails to disclose or suggest this requirement.

As stated above, Meltzer does not even suggest that the logic assembly 56 depicted in FIG. 5 is located within a housing, other than the housing 50, 51 identified by the Examiner as being the overmold required by the claim. Further, because the Examiner apparently overlooked the recitation in claim 42 of a therapy delivery circuit that delivers stimulation as controlled by the logic circuitry, the Examiner has not identified any teaching or suggestion of this requirement in Meltzer. Even assuming for the sake of argument that Meltzer did disclose another housing for the logic assembly that was located within the housing 50, 51, Meltzer would not have suggested that such a housing also includes a therapy delivery circuit that delivers stimulation as controlled by the logic circuitry. Consequently, Meltzer does not disclose or suggest a housing that includes both control electronics and a therapy delivery circuit that delivers stimulation as

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controlled by the control electronics, and is at least partially encapsulated by an overmold, as required by independent claim 42.

Claim 55, which depends from claim 42, further requires that the therapy delivery circuit within the same housing as the control circuitry comprises a pulse generator. In rejecting claim 55, the Examiner stated that the battery 55 and/or capacitors 52, 54 depicted in FIG. 5 of Meltzer are pulse generation circuitry. However, even if the battery 55 and/or capacitors 52, 54 could be considered pulse generation circuitry that delivers stimulation as controlled by control circuitry, as required by claim 55, Meltzer would still fail to meet the other requirements of claim 55.

In particular, Meltzer does not disclose or suggest including the capacitors in a housing with logic circuitry 56, the housing being at least partially encapsulated within members 50, 51. Indeed, the sizes and arrangements of the capacitors and logic circuitry on flex-circuit 52 as depicted in FIG. 5 would seem to have precluded inclusion of both in such a housing. Accordingly, one of ordinary skill would not have considered modification of the Meltzer device to include a housing within members 50, 51 that includes the logic circuitry and capacitors to be obvious.

Moreover, the Examiner has identified the battery in Meltzer as being both the power source and pulse generation circuitry. However, claim 55 requires that a power source be in a separate housing from the housing that contains the logic circuitry and the pulse generation circuitry. In other words, in view of the requirements of claim 55, the Examiner's construction would require the battery to be in two different housings at the same time, which is certainly not even remotely suggested by Meltzer.

As another example, Meltzer fails to disclose or suggest a conductor that extends from a lead connection module to the first module, wherein the first housing comprises a hermetic feedthrough to receive the conductor and the conductor electrically couples an electrode to the first module, as required by each of dependent claims 19, 36 and 52. In rejecting these claims, the Examiner merely stated that a "lead 59, lead connector 58 and connector port 57 can be seen in FIG. 5."³ This statement appears to be in reference to the other recited requirement of claims 19, 36 and 52 of "a lead connection module formed within the overmold to receive one of a lead that include an electrode and a lead extension that is coupled to the lead." Therefore, it appears

³ Final Office Action, page 3.

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that the Examiner did not consider or address the additional requirement of a conductor that extends from a lead connection module to the first module, wherein the first housing comprises a hermetic feedthrough to receive the conductor and the conductor electrically couples an electrode to the first module.

In any event, the depiction of the lead 59, lead connector 58 and connector port 57 in FIG. 5 would not have even suggested the identified additional requirement of claims 19, 36 and 52 to one of ordinary skill in the art. For example, neither the lead, 59, lead connector 58, connector port 57, nor any other feature depicted in FIG. 5 would have suggested a housing, at least partially encapsulated by an overmold, and comprising a hermetic feedthrough to receive a conductor from a lead connection module formed within the overmold, as required by claims 19, 36 and 52.

In order to support an anticipation rejection under 35 U.S.C. § 102(b), it is well established that a prior art reference must disclose each and every element of a claim. This well known rule of law is commonly referred to as the "all-elements rule."⁴ If a prior art reference fails to disclose any element of a claim, then rejection under 35 U.S.C. § 102(b) is improper.⁵

Meltzer fails to disclose each and every limitation set forth in claims 1, 2, 11, 13-17, 19-23, 33-34, 36-42 and 51-55. For at least these reasons, the Examiner has failed to establish a prima facie case for anticipation of these claims under 35 U.S.C. § 102(b). Withdrawal of this rejection is requested.

Claim Rejection Under 35 U.S.C. § 103

In the Final Office Action, the Examiner rejected claims 18 and 35 under 35 U.S.C. § 103(a) as being unpatentable over Meltzer, and rejected claims 3-10, 12, 24-31, 43-50 and 56-57 under 35 U.S.C. § 103(a) as being unpatentable over Meltzer in view of Munshi et al. (US 5,411,537, hereinafter "Munshi"). Applicant respectfully traverses the rejection. The applied references fail to disclose or suggest the inventions defined by Applicant's claims, and provide

⁴ See *Hybritech Inc. v. Monoclonal Antibodies, Inc.*, 802 F.2d 1367, 231 USPQ 81 (CAFC 1986) ("it is axiomatic that for prior art to anticipate under 102 it has to meet every element of the claimed invention").

⁵ *Id.* See also *Lewmar Marine, Inc. v. Bartent, Inc.* 827 F.2d 744, 3 USPQ2d 1766 (CAFC 1987); *In re Bond*, 910 F.2d 831, 15 USPQ2d 1566 (CAFC 1990); *C.R. Bard, Inc. v. MP Systems, Inc.*, 157 F.3d 1340, 48 USPQ2d 1225 (CAFC 1998); *Oney v. Ratliff*, 182 F.3d 893, 51 USPQ2d 1697 (CAFC 1999); *Apple Computer, Inc. v. Articulate Systems, Inc.*, 234 F.3d 14, 57 USPQ2d 1057 (CAFC 2000).

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no teaching that would have suggested the desirability of modification to arrive at the claimed invention.

Initially, Applicant notes that Munshi provides no teaching that would have overcome the deficiencies of Meltzer with respect to the requirements Applicant's independent claims discussed above. For at least this reason, the Examiner has failed to establish a *prima facie* case for non-patentability of Applicant's claims 3-10, 12, 15, 24-31, 35, 43-50 and 56-57 under 35 U.S.C. § 103(a), and the rejections of each of these claims should be withdrawn. Moreover, the applied references, either alone or in combination, fail to teach or suggest a number of the additional requirements recited in these claims.

Claims 18 and 35

For example, the applied references fail to disclose or suggest first and second housings, at least partially encapsulated by an overmold, that are cylindrical, as required by claims 18 and 35. The Examiner has cited no prior art teaching of this requirement within the record. Instead, the Examiner merely argued that it would have been obvious to one of ordinary skill to modify the shapes of the modules taught by Meltzer to be cylindrical since it was known in the art to modify medical device components to yield smaller and lighter devices.

The Examiner's argument is legally insufficient to make out a *prima facie* case of obviousness for several reasons. For example, as discussed above, the Examiner has cited no teaching of substantially cylindrical housings in the record. Further, the Examiner has cited no evidence suggesting that one of ordinary skill in the art would have selected substantially cylindrical housings, as opposed to the myriad other possible shapes, to make a medical device smaller and lighter. In other words, with respect to the particular shape of the first and second housings recited in claims 18 and 35, the Examiner appears to be improperly relying on mere conjecture and improper assertions that the requirements of Applicant's claims would have been "obvious to try" or a matter of "design choice."

The Court of Appeals for the Federal Circuit has specifically addressed the evidentiary standard required to uphold an obviousness rejection.⁶ The Federal Circuit held that the factual questions material to patentability cannot be resolved on subjective belief and unknown

⁶ *In re Lee*, 61 USPQ2d 1430 (CAFC 2002).

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authority.⁷ In other words, a *prima facie* case of obviousness must be based upon substantial evidence, and not subjective musings or conjecture by the Examiner.⁸ Deficiencies in the evidentiary record cannot be cured by general conclusions such as "general knowledge" or "common sense."⁹ Accordingly, the Examiner cannot rely on unsupported, conclusory statements to close holes in the evidentiary record.¹⁰ Unless the Examiner can establish an evidentiary record based on concrete prior art references that establish that it would have been obvious to a person with ordinary skill in the art to modify Meltzer to include first and second housings, at least partially encapsulated by an overmold, that are cylindrical, claims 18 and 35 should be allowed.

Moreover, one of ordinary skill in the art would have appreciated that the device depicted in FIG. 5 of Meltzer is configured to be as thin in one dimension as possible. One of ordinary skill would have recognized that modification of this device described by Meltzer to rearrange its components into two cylindrical housings within members 50, 51 would not have furthered this purpose evident in Meltzer, or made the device lighter or smaller as suggested by the Examiner. Indeed, one of ordinary skill would have appreciated that such a modification would likely have made the device, thicker, larger and heavier. Accordingly, one of ordinary skill would have consciously avoided the modification to Meltzer proposed by the Examiner, *particularly* if they were motivated to make the device smaller and lighter, as suggested by the Examiner.

Claims 5-10, 26-31, 45-50, 56 and 57

These claims recite numerous features that are not disclosed or suggested in either Meltzer or Munshi. For example, claims 5, 26 and 45 require a recharge coil within an overmold that substantially encircles first and second modules. Claims 6, 27 and 46 require a third module that includes a third housing that houses the recharge coil. Claims 7, 28 and 47 further require that the overmold at least partially encapsulates the third module. Claims 8, 29 and 48 further require that the first, second and third modules are positioned within the overmold in one of a triangular configuration or a linear configuration in which the modules are positioned

⁷ *Id.* at 1434.

⁸ *In re Lee*, 61 USPQ2d at 1634.

⁹ *Id.*

¹⁰ *Id.*

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substantially along a common axis. Claims 9, 30 and 49 require that the third module is located outside of the overmold, and that a flexible tether member connects the third module to the overmold. Claims 10, 31 and 50 require that the flexible tether member comprises a helix. Further, independent claim 56 requires control electronics and a rechargeable power source within a first housing, a recharge coil within a second housing, and a flexible tether member that connects the first and second housings, while dependent claim 57 requires that the tether member comprises a helix.

Again, the combination of Meltzer and Munshi fails to disclose or suggest any of these numerous requirements of Applicant's claims. Further, the Examiner's argument *admits* that Meltzer and Munshi fail to disclose or suggest any of these requirements.¹¹ Moreover, the Examiner has cited no teaching *in the prior art* that would have motivated one of ordinary skill in the art to make the significant modifications to Meltzer necessary to meet the requirements of the claims.

To overcome the deficiencies in Meltzer and Munshi, instead of evidence supporting a *prima facie* case of obviousness for any of claims 5-10, 26-31, 45-50, 56 and 57, the Examiner again repeatedly relies on improper assertions such as "design choice." As discussed above with reference to claims 18 and 35, the Federal Circuit has held that such unsupported arguments are legally insufficient to establish a *prima facie* case of obviousness. Accordingly, the rejections of these claims must be withdrawn.

With respect to a number of these claims, the Examiner argued that recited features are a mere rearrangement of parts. However, for many of these claims, Meltzer and Munshi fail to even disclose or suggest "the parts." Even if "mere rearrangement of parts" was a valid argument to overcome a complete lack of evidence that the claimed features were disclosed or suggested in the prior art, and thereby establish a *prima facie* case of obviousness, it would still fail to establish a *prima facie* case of obviousness in situations where the prior art does not even teach or suggest the parts to rearrange.

For a number of the claims above, Meltzer and Munshi fail to disclose "the parts." For example, Meltzer and Munshi fail to disclose or suggest a third module including a third housing that houses a recharge coil, as required by claims 6, 27 and 46. Meltzer and Munshi also fail to

¹¹ Final Office Action, pages 5 and 6.

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disclose or suggest a flexible tether member connects the third module to an overmold, as required by claims 9, 30 and 49. Meltzer and Munshi also fail to disclose or suggest a tether member that comprises a helix, as required by claims 10, 31 and 50. Further, Meltzer and Munshi fail to disclose or suggest control electronics and a rechargeable power source within a first housing, a recharge coil within a second housing, and a flexible tether member that connects the first and second housings, as required by independent claim 56, or a tether member comprising a helix, as required by dependent claim 57. Accordingly, for at least these claims, the "mere arrangement of parts" argument does not apply, and the Examiner has therefore failed to establish a prima facie case of obviousness.

The Examiner cited *In re Japikse*, 86 USPQ 70 (CCPA 1950), and MPEP 2144.04 in support of the "mere arrangement of parts" argument. However, a more recent decision also cited in MPEP 2144.04 appears to call into question the continuing validity of the "mere arrangement of parts" argument of *In re Japikse*. In particular, in *Ex parte Chicago Rawhide Mfg. Co.*, 223 USPQ 351, 353 (Bd. Pat. App. & Inter. 1984), the Board held that "[t]he mere fact that a worker in the art could rearrange the parts of the reference device to meet the terms of the claims on appeal **is not by itself sufficient to support a finding of obviousness. The prior art must provide a motivation or reason** for the worker in the art, without the benefit of [Applicant's] specification, to make the necessary changes in the reference device."¹²

Further, as discussed above, the Court of Appeals for the Federal Circuit recently addressed the evidentiary standard required to uphold an obviousness rejection.¹³ Specifically, the Federal Circuit held that a prima facie case of obviousness must be based upon substantial evidence, and not subjective musings or conjecture by the Examiner.¹⁴ This holding of the Federal Circuit precludes reliance on a "mere arrangement of parts" argument in the absence of any evidence of motivation, as has been done by the Examiner.

Moreover, the holding of *In re Japikse* is limited to situations in which the modification does not change the operation of the device, such as changing the position of a starting switch, which was the modification before the Court in that *Japikse*. The Examiner has not established that the modifications of the Meltzer device necessary to meet the requirements of Applicant's

¹² Emphasis added.

¹³ *In re Lee*, 61 USPQ2d 1430 (CAFC 2002).

¹⁴ *Id.*

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claims would not have affected the operation of the Meltzer device. In fact, one of ordinary skill in the art would have recognized that such modifications would have impacted the size and shape of the device, as well as other operational characteristics such as the electromagnetic interaction of the various components of the device, all of which one of ordinary skill would have recognized as important operational characteristics of a medical device.

With reference to the requirement in claims 10, 31, 50 and 57 of a helix tether, the Examiner further argued that it would have been obvious to one of ordinary skill to modify Meltzer to include such a tether because:

Applicant has not disclosed [that] the helix tether provides an advantage, is used for a particular purpose, or solve [sic] a stated problem. One of ordinary skill in the art, furthermore, would have expected the Applicant's invention to perform equally well with a non-helix tether, since both tether would join the medical device.¹⁵

It is the Examiner's burden to establish a prima facie case of obviousness with substantial evidence in the record of references that disclose the features of Applicant's claims and of a motivation to modify or combine the references.¹⁶ When the Examiner fails to do so, as is the case in the present application, it is improper for the Examiner to attempt to shift the burden to Applicant. The Applicant does not have to prove the non-obviousness in the first instance by identifying advantages, unexpected results, or the like. In any event, as indicated at paragraph [0072] of Applicant's description, use of a helix tether may allow a "recharge module freedom of movement some significant distance away from other modules 30 and 32. Recharge module 34 can be moved to improve inductive coupling for energy transfer and/or the cosmetics of modular IMD 120 when implanted on cranium 12."

In sum, the rejections under section 103 are not supported by evidence, and instead depend entirely on legally improper reasoning. For at least this reason, the Examiner has failed to establish a prima facie case for non-patentability of Applicant's claims 3-10, 12, 15, 24-31, 35, 43-50 and 56-57 under 35 U.S.C. § 103(a). Withdrawal of these rejections is requested.

¹⁵ Final Office Action, page 6.

¹⁶ *In re Lee*, 61 USPQ2d 1430 (CAFC 2002).

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Rejection for Obviousness-type Double Patenting:

The Examiner provisionally rejected claims 1-31 and 33-57 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-23 of copending Application No. 10/731,638 (US Patent Publication 20040176817). Applicant notes the provisional status of this rejection. Accordingly, Applicant will address this issue if and when the rejection is formally applied.

CONCLUSION

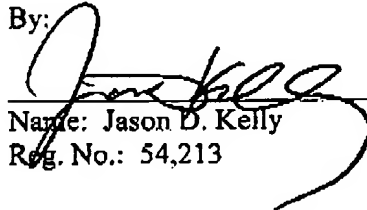
All claims in this application are in condition for allowance. Applicant respectfully requests reconsideration and prompt allowance of all pending claims. Please charge any additional fees or credit any overpayment to deposit account number 50-1778. The Examiner is invited to telephone the below-signed attorney to discuss this application.

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5/23/06

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